

## **BIAXIAL ARTIFICIAL DISC REPLACEMENT**

### **REFERENCE TO RELATED APPLICATION**

This application claims priority from U.S. Provisional Patent Application Serial No. 60/420,169, filed October 22, 2002, the entire content of which is incorporated herein by reference.

### **5 FIELD OF THE INVENTION**

This invention relates generally to artificial disc replacement (ADR) and, in particular, to ADRs including cushioning components to protect the implant from excessive force.

### **BACKGROUND OF THE INVENTION**

10 Improvements in prosthetic intervertebral disc and joint replacement components, and related surgical procedures, have led to dramatic increases in implant longevity. Many artificial hip and knee components now last for twenty years or more due to improved materials and greater insight into movement, load distribution and wear characteristics.

15 Many spinal conditions, including degenerative disc disease, can now be treated through artificial disc replacement (ADR), which has several advantages over spinal fusion. The most important advantage of ADR is the preservation of spinal motion. Spinal fusion eliminates motion across the fused segments of the spine. Consequently, the discs adjacent to the fused level are subjected to increased stress, which increases the  
20 changes of future surgery to treat the degeneration of the discs adjacent to the fusion.

One of the most important features of an artificial disc replacement (ADR) is its ability to replicate the kinematics of a natural disc. ADRs that replicate the kinematics of a normal disc are less likely to transfer additional forces above and below the replaced disc. In addition, ADRs with natural kinematics are less likely to stress the facet joints

and the annulus fibrosus (AF) at the level of the disc replacement. Replicating the movements of the natural disc also decreases the risk of separation of the ADR from the vertebrae above and below the ADR.

In an attempt to replicate natural disc movements various ADR materials have been tried, including hydrogels, metal and rubber. As one example, U.S. Patent No. 6,602,291 resides in a prosthetic spinal disc nucleus comprising a hydrogel core surrounded by a constraining jacket. The hydrogel core is configured to expand from a dehydrated state to a hydrated state. In the dehydrated state, the hydrogel core has a shape selected to facilitate implantation through an annulus opening. Further, in the hydrated state, the hydrogel core has a shape corresponding generally to a portion of a nucleus cavity, the hydrated shape being different from the dehydrated shape. Upon hydration, the hydrogel core transitions from the dehydrated shape to the hydrated shape.

Unfortunately, the flexibility of the hydrogel and the constraining jacket allow hydrogel ADRs to change shape and extrude through defects in the annulus through which the ADR was inserted, for example. My U.S. Patent Nos. 6,245,107, 6,371,990, 6,454,804, and published applications WO 01/10316 A1; 20020156533; 20020165542; 20030004574; 20030040796; and 20030078579 are useful in addressing such problems.

Metal and rubber ADRs, on the other hand, also frequently fail at the metal-rubber interface. The rubber fails directly due to high shear stresses or because the rubber separates from the metal. Clearly any improvements in these and other areas would be welcomed by the medical community and by patients undergoing procedures to implant prosthetic components of this kind.

## SUMMARY OF THE INVENTION

This invention broadly resides in an ADR that protects a cushioning component from excessive force. In the preferred embodiment, physical features on the front and/or back of the ADR enable the device to replicate the normal movements of the spine through predetermined, limited, movements of the endplate components relative to one another. For example, though not limited to these characteristics, the components of the

ADR could be dimensioned to allow 15 degrees of flexion, 5 degrees of extension, 5 degrees of lateral bending, and 1-2mm of translocation.

5 In the preferred embodiment the physical features are axles that extend through overlapping lateral portions associated with the endplate components. A desirable configuration includes a pair of axles, one in the anterior portion and another in the posterior portion, wherein some or all of the axles extend through an oversized aperture that allows the limited relative movement of the endplate components. Alternatively, the anterior and posterior physical features may include mating projections and depressions to permit a desired degree of relative movement.

#### 10 BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a view of the lateral aspect of the spine and an ADR according to the present invention;

FIGURE 2 is a view of the anterior aspect of the spine and the ADR;

FIGURE 3 is a view of the lateral aspect of a flexed spine and the ADR;

15 FIGURE 4 is a view of the anterior aspect of a spine in lateral bending and the ADR;

FIGURE 5A is a coronal cross section of one configuration wherein four axles connect the endplates;

FIGURE 5B is a coronal cross section of an alternative embodiment;

20 FIGURE 5C shows how the component nests in each other;

FIGURE 6A is a view of the lateral aspect of the ADR with optional screws to fix the ADR to the vertebrae;

FIGURE 6B is a frontal view with an emphasis on screw orientation;

25 FIGURE 7A is a view of the lateral aspect of an alternative embodiment of the ADR;

FIGURE 7B is a view of the top of the ADR drawn in Figure 7A;

FIGURE 8 is a view of the lateral aspect of an alternative embodiment of the ADR drawn in Figure 7A;

FIGURE 9A is a view of the lateral aspect of the spine and the superior endplate of the ADR;

FIGURE 9B is a view of the lateral aspect of the spine and the insertion of the inferior endplate;

5       FIGURE 9C shows insertion of the elastomeric component;

FIGURE 9D shows insertion of the anterior plate onto the inferior endplate of the ADR;

FIGURE 10A is a view of the lateral aspect of another embodiment of the present invention;

10       FIGURE 10B is a view of the anterior aspect of the device drawn in Figure 10A;

FIGURE 11A is a view of the lateral aspect of yet a further alternative embodiment of the ADR; and

FIGURE 11B is a view of the lateral aspect of the device drawn in Figure 11A.

#### DETAILED DESCRIPTION OF THE INVENTION

15       Figure 1 is a view of the lateral aspect of the spine and an ADR according to the invention depicted generally at 100. A top endplate component 102 articulates with a bottom endplate component 104 through axles 106, 108 in the front and back of the ADR. A cushioning component 120 is disposed between the endplate components 102, 104. Holes 110, 112 of the bottom endplate component receive the axles 106, 108 and are  
20       sized to allow normal movements of the spine, preferably a limited amount of flexion, extension, lateral bending, and/or translocation. Depending upon the type and degree of desired movement, over-sized holes may be provided on the top endplate component, or both components 102, 104.

25       The endplate components are preferably made of metal, and the surface of each endplate component adjacent to the vertebrae would preferably incorporate a bone-ingrowth promoting surface of the types known to those skilled in orthopaedic design. The cushion component 120 would likely be an elastomer, though contained hydrogels and other compressible synthetic and natural members may alternatively be used. The

invention is not limited in this regard. The cushion component 120 would be held in position between the endplate components 102, 104 by lips around the periphery of the endplate components. As such, the cushioned 102 component would not need to be bonded to the endplate components.

5        Figure 2 is a view of the anterior aspect of the spine and the ADR. Note that the various components are preferably sized to facilitate lateral bending. Figure 3 is a view of the lateral aspect of a flexed spine and the ADR, better revealing how the anterior axle travels to the inferior aspect of the hole in the bottom endplate component. The posterior axle travels to the top of the posterior hole in the bottom endplate component. Figure 4 is  
10    a view of the anterior aspect of a spine in lateral bending and the ADR. As discussed above, the top endplate component could impinge against the bottom endplate component after a level of lateral bending such as 5 degrees.

      The articulations between the two-endplate components 102,104 limit the forces experienced by the cushion component 120. For example, the cushion component 120  
15    may be protected from excessive shear. The dimensions of the endplate components 102, 104 may further be dimensioned and/or proportioned to protect the cushion component 102 from excessive axial loads. As best seen in Figure 4, the top and bottom endplate components 102, 104 may be designed to impinge after a certain amount of compression of the cushion component 120. Such impingement between the top and bottom endplate  
20    components would also help to protect the axles 106,108. In addition, impingement of the endplate components 102, 104 should help protect the facet joints and remaining annulus fibrosis from excessive force.

      The axles may or may not extend through the cushion component. Figure 5A is a coronal cross section of one configuration wherein four axles connect the endplates.  
25    Figure 5B is a coronal cross section of an alternative embodiment wherein two axles connect the endplates. Note that although separate elements are shown for the endplate components and axles, the axles may be integral to one of the components, particularly the component that nests in the other, as shown in Figure 5C.

Figure 6A is a view of the lateral aspect of the ADR with optional screws to fix the ADR to the vertebrae. Figure 6B is a front view. In the preferred embodiments, the ADR would incorporate some mechanism to prevent the screws from backing out.

Figure 7A is a view of the lateral aspect of an alternative embodiment of the ADR. Figure 7B is a view of the top of the ADR drawn in Figure 7A. In this case, hemi-cylindrical projections 702 from the upper endplate articulate with hemi-piston projections 704 from the lower endplate. As described above the articulations between the endplates permit normal spinal movement and cushioning. The endplates also prohibit excessive movements and excessive forces between the endplates.

Figure 8 is a view of the lateral aspect of an alternative embodiment of the ADR drawn in Figure 7A, including a removable plate 802 associated with the lower endplate allows assembly of the ADR within the disc space. The shape of the endplates, the articulations between the endplates, and the removable plate hold the elastomer in place between the endplates. Again, the elastomer need not be glued to the endplates.

Figures 9A-9D illustrate an insertion sequence applicable to the ADR drawn in Figure 8. Figure 9A is a view of the lateral aspect of the spine and the superior endplate 804 of the ADR. Spikes 806 on the endplate are press fit into the vertebral endplate 810 using a distraction instrument 812. Figure 9B is a view of the lateral aspect of the spine and the insertion of the inferior endplate 814. The distraction instrument 812 fits into the upper and lower ADR endplates to assure the inferior endplate is properly aligned with respect to the superior endplate of the ADR. Figure 9C shows insertion of the elastomeric component. Figure 9D shows insertion of the anterior plate onto the inferior endplate of the ADR. A screw or screws holds the anterior plate on the inferior endplate of the ADR.

Figure 10A is a view of the lateral aspect of another embodiment of the invention. Figure 10B is a view of the anterior aspect of the device drawn in Figure 10A. A lip 1002 on the posterior aspect of the inferior endplate 1004 prevents the superior endplate 1006 from sliding forward. The tongue-like projections 1008, 1010 of the superior and inferior endplates cooperate to limit lateral bending, for example to 5 degrees in either

direction. The posterior projections from the superior endplate can also limit extension; to 5 degrees, for example. A movable clip 1020 prevents the elastomer 1022 from falling out of the front of the device. The elastomer may have a thin sheet of metal glued to its superior and inferior surfaces. The low friction of the metal sheets would facilitate movement of the elastomer between the endplate components.

Figure 11A is a view of the lateral aspect of yet a further alternative embodiment of the ADR. The projections from the inferior endplate have retractable extensions. The extensions 1102, 1104 help hold the elastomer in position without interfering with the motion of the two endplate components. The endplate components do not cooperate to limit lateral bending in this embodiment. The dotted line represents the outline of the portion of the retractable projection that lies within a recess of the projection from the inferior endplate. Figure 11B is a view of the lateral aspect of the device drawn in Figure 11A. The retractable projections are drawn in an elevated position.

I claim: